

K132913 Page 1 of 3

GE Healthcare

NOV 0 8 2013

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: September 16, 2013

Submitter: GE Healthcare [GE Healthcare Austria GmbH & Co OG]

Tiefenbach 15 Zipf. Austria 4871

Primary Contact Person: Bryan Behn

Regulatory Affairs Manager

GE Healthcare T:(414)721-4214 F:(414)918-8275

Secondary Contact Person: Roland Kuntscher

Regulatory Affairs Specialist

GE Healthcare Austria GmbH & Co OG

T:(++43)7682-3800-660 F:(++43)7682-3800-47

Device: Trade Name: Voluson E Series

Models: Voluson E6/E8/E8Expert/E8Expert Limited Edition/

E10 Diagnostic Ultrasound Systems

Common/Usual Name: Voluson E6/E8/E8/Expert/E8/Expert Limited Edition/E10

Classification Names: Class II

Product Code: Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN

Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Predicate Device(s): K131267 Voluson E-Series E6/E8/E8Expert/E8Expert LE/E10

Diagnostic Ultrasound System

<u>Device Description:</u> The Voluson E-Series system is a full-featured Track 3

ultrasound system, primarily for general radiology use and specialized for OB/GYN with particular features for realtime 3D/4D acquisition. It consists of a mobile console with keyboard control panel; color LCD/TFT touch panel, color video display and optional image storage and printing devices. It provides high performance ultrasound imaging and analysis and has comprehensive networking and DICOM capability. It utilizes a variety of linear, curved linear, matrix phased array transducers including mechanical and electronic scanning transducers, which provide highly accurate realtime three dimensional imaging

supporting all standard acquisition modes.



510(k) Premarket Notification Submission

Device Modification:

This modification consists of a change to the labeling for the previously cleared SonolT feature. Additionally, the previously cleared probe RAB4-8-D had been re-introduced to the Voluson E Series and a correction to the transducer application Obstetrics on the 9L-D have been made since the previous clearance.

Intended Use:

The device is a general purpose ultrasound system. Specific clinical applications remain the same as previously cleared: Fetal/OB: Abdominal (including GYN, pelvic and infertility monitoring/follicle development): Pediatric: Small Organ (breast, testes, thyroid etc.): Neonatal and Adult Cephalic: Cardiac (adult and pediatric): Musculo-skeletal Conventional and Superficial: Peripheral Vascular: Transvaginal: Transrectal

Technology:

The Voluson E-Series employs the same fundamental scientific technology as its predicate devices.

<u>Determination of</u> Substantial Equivalence:

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform with applicable medical device safety standards. The Voluson E-Series and its applications comply with voluntary standards:

- 1. IEC60601-1. Medical Electrical Equipment Part 1: General Requirements for Safety
- 1EC60601-1-2, Medical Electrical Equipment –
 Part 1-2:General Requirements for Safety Collateral
 Standard: Electromagnetic Compatibility
 Requirements and Tests
- 3. IEC60601-2-37, Medical Electrical Equipment –
 Part 2-37:Particular Requirements for the Safety of
 Ultrasonic Medical Diagnostic and Monitoring
 Equipment
- 4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 5. ISO10993-1. Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing-Third Edition
- 6. NEMA UD 2. Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

K 132913 Page 3f3



GE Healthcare

510(k) Premarket Notification Submission

- 7. ISO14971. Application of risk management to medical devices
- 8. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission. Voluson E Series, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the Voluson E Series to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G009 Silver Spring, MD 20993-0002

November 8, 2013

GE HEALTHCARE BRYAN BEHN REGULATORY AFFAIRS MANAGER 9900 W INNOVATION DRIVE WAUWATOSA WI 53226

Re: K132913

Trade/Device Name: Voluson E6 / E8 / E8expert / E8expert Limited Edition / E10

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed Doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX Dated: October 22, 2013 Received: October 24, 2013

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Voluson E6 / E8 / E8expert / E8expert Limited Edition / E10 Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

RAB2-5-D	<u>P2D</u>	<u>3Sp-D</u>
RIC5-9-D	<u>P6D</u>	<u>C4-8-D</u>
RNA5-9-D	<u> 11L-D</u>	<u>RAB6-D</u>
4C-D	<u>C1-5-D</u>	<u>eM6C</u>
IC5-9-1)	<u>ML6-15-D</u>	<u>S4-10-D</u>
RSP6-16-D	<u>RM6C</u>	<u>RAB4-8-D</u>
RIC6-12-D	<u>RRE5-10-D</u>	
<u>9L-D</u>	<u>RM14L</u>	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.ida.gov/MedicalDevices/Resources/orYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.ida.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris

Director

Division of Radiological Health Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

for

Enclosure



GE Healthcare 510(k) Premarket Notification Submission

510(k) Number (if known): K132913

Device Name: Voluson E-Series (Voluson E6/E8/E8/Expert/E8/Expert Limited

Edition/E10) Diagnostic Ultrasound Systems

Indications for Use:

The device is a general purpose ultrasound system. Specific clinical applications remain the same as previously cleared: Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development): Pediatric; Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiae (adult and pediatric); Musculoskeletal Conventional and Superficial; Peripheral Vascular; Transvaginal; Transrectal

Prescription Use_X(Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_NA_ (Part 21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE B	ELOW THIS LINE IF NEEDED	: - CONTINUE ON ANOTHER PAGE 9)
Concurrence of CDRH, Office	of In Vitro Diagnos	sties and Radiological Health (OIR)

Page 1 of 24



GE Healthcare 510(k) Premarket Notification Submission

Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Voluson E Series system and for all of its probe/mode combinations. Combinations identified as "P" represents those previously cleared with the unmodified Voluson E6/E8/E8Expert/E10 and "E" are those that have been added by Appendix E of the FDA Ultrasound guidance. This modification did not add to the previously cleared system level or transducer indications or clinical applications.



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form GE Voluson E-Series

(Voluson E6/E8/E8Expert/E8Expert Limited Edition/E10)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

 		,	, _	·	Me	ode of Ope	ration				
Clinical Application Anatomy Region of Interest	B	М	PW Doppler	CW Onppler	Color ^e Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other [Notes
Ophthalmic				_			<u> </u>	<u> </u>			
Fetal / Obstetries ⁽²⁾	P	Р	P	P	P	P	P	P	P	P	5.6.9
Abdominal ¹¹	P	Р	P	P	Р	P	P	Р	P	P	9,6,9
Pediatric	P	P	P	Р	P	р	P	Р	P	P	5,6,9
Small Organi21	P	P	P	P	P	P	P	P	P	P	5,6,9
Neonatal Cephalic	P	P	P	Р	P	P	Р	P	P	4	[5]
Adult Cephalic	Р	Р	ч	P	P	P	Р	Р	P	P	
Cardiac ¹¹	P	P	P	Р	P	Р	Р	P	Р	P	151
Peripheral Vascular	Р	Р	P	P	P	P	P	Р	P	P	5,6,9
Musculo-skeletal Conventional	P	P	Р		P	Ρ	P	P	Р	P	[5,6,9
Musculo-skeletal Superficial	Р	Р	P		Р	P	Р	P	Р	Р	1.5,6,9
Other								ļ	ļ		
Exam Type, Means of Access		L									
Transesophageal			<u> </u>								
Transrectal ^(*)	Р	P	Р		P	P	Р	P	Р	P	[5,6,9
Transvaginal	Р	P	P		P	Р	Р	P	Р	P	[5,6,5
Transuretheral										_	
Intraoperative								<u> </u>	L		<u> </u>
Intraoperative Neurological								_			
Intravascular				<u> </u>					ļ		
Laparoscopic		1							[l	<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

- [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
- [3] Cardiac is Adult and Pediatric.
- [5] 3D/4D Imaging Mode.
- [6] Includes imaging of guidance of biopsy (2D/3D/4D).
- [7] Includes infertility monitoring of follicle development.
- [8] Includes urology/prostate.
- (9) Elastography imaging- Elasticity
- (*) Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- (*) 4D color Doppler

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Prescription User (Per 21 CFR 801.109)

Page 2 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form GE Voluson E Series with RAB2-5-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Мо	de of Oper	ation				
Clinical Application Anatomy Region of Interest	В	М	PW Doppler	CW Doppler	Color Dappler	Color M Doppler	Power Dappler		Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic					<u> </u>						
Fetal / Obstetrics ⁽²⁾	P	Р	P	P	P	Р	P	Р	Р	Р	[5.6]
Abdominal ⁽¹⁾	P	P	P	P	Р	P	P	P	P	P	[5.6]
Pediatric			<u> </u>								
Small Organ ^{i2r}											
Neonatal Cephalic					<u> </u>						
Adult Cephalic											
Cardiac ^M											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial								<u></u>			
Other			<u> </u>		<u> </u>						
Exam Type, Means of Access			<u> </u>								
Transesophageal											
Transfectal											<u> </u>
Transvaginal			<u> </u>								
Transuretheral		Ĺ	<u> </u>					<u> </u>			
Intraoperative			<u> </u>					<u> </u>			
Intraoperative Neurological			<u> </u>	<u> </u>	ļ			ļ			
Intravascular					<u> </u>						ļ
Laparoscopic		L			<u> </u>			<u>.</u>	<u> </u>		

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Page 3 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RIC5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					М	ode of Ope	ration		····		
Clinical Application Anatomy Region of Interest	В	м	PW Doppler	CW Dappler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ²⁴	P	Ą	P		P	Р	P	Р	P	P	[5,6,9]
Abdominal ^[1]											
Pediatric											
Small Organ ⁽²⁾									·		
Neonatal Cephalic											
Adult Cephalic											
Curdiac ⁽¹⁾											
Peripheral Vascular			1								
Musculo-skeletal Conventional	·		1								
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access			<u> </u>								
Transesophageal			1		<u>. </u>						
Transrectal ^[4]	P	P	P	<u> </u>	Р	P	P	Р	P	P	[5,6,9]
Transvaginal	P	P	Р		P	P	P.	P	P	P	[5,6,9]
Transuretheral								<u> </u>	<u> </u>		
Intraoperative					٠						
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA. E = added under Appendix E

Notes [5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of hopsy (3D4D).

[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[9] Elastography Imaging- Elasticity

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)

Page 4 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RNA5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy: Region of Interest	B	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic			<u> L</u>	L						•	
Fetal / Obstetrics ^[7]	P	P	P	P	P	Р	Р	P	Ρ	Р	[5,6]
Ahdominal ^{III}	P	Р	P	Р	P	P	Р	P	P	P	[5,6]
Pediatric	P	P.	P	P	P	P	P	Р	P	Р	[5,6]
Small Organ ⁽²⁾	P	ľ	P	þ	P	P	P	P	Р	Р	[5,6]
Neonatal Cephalic	P	Р	P	P	P	P	P	P	P	Р	1.51
Adult Cephalic	•										
Cardiac ^{F1}	P	Р	Р	P	р	P	Р	P	Р	P	[5]
Peripheral Vascular	Р	P	Р	Р	P	Р	P	Р	P	P	[5,6]
Musculo-skeletal Conventional	P	P	Р	P	P	P	Р	Р	Р	P	[5,6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access				<u> </u>							
Transesophageal		<u> </u>									
Transrectal ^{pq}											
Transvaginal											
Transuretheral			ļ <u>.</u>								<u> </u>
Intraoperative											
Intraoperative Neurological											<u> </u>
Intravascular											
Laparoscopic							L				<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal is Neonatal and pediatric

- [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
- [3] Cardiac is Neonatal and Pediatric
- {5} 3D/4D Imaging Mode
- [6] Includes imaging of guidance of biopsy (3D/4D)
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)

Page 5 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form <u>GE Voluson E Series with 4C-D Transducer</u>

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy: Region of Interest	В	М	PW Doppler	CW Doppler	Culor Doppler	Color M Doppler	Power Doppler	Combined Modes	Hurmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic		<u> </u>	<u> </u>				<u> </u>				
Fetal / Obstetrics ^[7]	Р	Р	P	P	P	P	Р	P	P	P.	[6]
Abdominal ⁽¹⁾	Р	P	P	P	P	P	Р	P	P	P	[6]
Pediatric					<u> </u>						<u> </u>
Small Organ ^[2]			<u>l</u>								<u> </u>
Neonatal Cephalic											
Adult Cephalic	·										<u> </u>
Cardiac ¹³											
Peripheral Vascular	P	٦.	P	P	Р	Р	P	Р	P	P	[6]
Musculo-skeletal Conventional			<u> </u>								<u> </u>
Musculo-skeletal Superficial								<u></u>			ļ
Other								<u> </u>			<u> </u>
Exam Type, Means of Access			<u> </u>								<u> </u>
Transesophageal			ļ		ļ						ļ <u>.</u>
Transrectal					ļ						ļ
Transvuginol		ļ <u> </u>	<u> </u>								ļ
Transuretheral											<u> </u>
Intraoperative			<u> </u>								<u> </u>
Intraoperative Neurological											
Intravascular			1								<u> </u>
Laparoscopic									٠	<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology

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- [6] Includes imaging of guidance of hiopsy (2D)
- [7] Includes intertility monitoring of follicle development
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD (PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

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Page 6 of 24



GE Healthcare 510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form GE Voluson E Series with IC5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy: Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic										_	
Fetal / Obstetrics 1	Р	P	17		ь	Р	Р	Р	Р	P	[6.9]
Abdominal ^[1]											
Pediatric			1								
Small Organ ⁽³⁾				i							
Neonatal Cephalic			<u> </u>	<u> </u>		<u> </u>					
Adult Cephalic							•				
Cardiac ¹⁹			 	 							
Peripheral Vascular			 								
Musculo-skeletal Conventional			 								
Musculo-skeletal Superficial			 						-		
Other			 								
Exam Type, Means of Access			<u> </u>								
Transesophageal			 								
Transrectal ^[1]	P	P	Р		Р	Р	P	Р	Р	Р	[6,9]
Transvaginal	P	17	P		Р	P	Р	Р	Ь	P	[6,9]
Transuretheral			1								
Intraoperative											
Intraoperative Neurological											
Intravascular		_						-			
Laparoscopic											

N = new indication: P = previously cleared by FDA: E = added under Appendix E

Notes: [6] Includes imaging of guidance of hiopsy (2D)

[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[9] Elastography Imaging- Elasticity

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)

Page 7 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RSP6-16-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application Anatomy Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other (Notes)		
Ophthalmic													
Fetal / Obstetries ^[2]			l										
Abdominal ⁽¹⁾													
Pediatric	₽	P	Р		Р	P	P	P	P	P	[5,6]		
Small Organ ⁽²⁾	Р	Р	P		P	P	4	Р	P	4	[5,6]		
Neonatal Cephalic													
Adult Cephalic			<u> </u>										
Cardiac ^{t ()}													
Peripheral Vascular	P	P	Р		P	Р	P	Р	P	_ P	[5,6]		
Musculo-skeletal Conventional	Р	P	P		P	۴	P	Р	P	P	[5,6]		
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5.6]		
Other													
Exam Type, Means of Access													
Transesophageal													
Transrectal ^[4]													
Transvaginal													
Transuretheral													
Intraoperative													
Introoperative Neurological						_							
Intravascular													
Laparoscopic													

N = new indication; P = previously cleared by FDA: E = added under Appendix E

Notes. [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Page 8 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RIC6-12-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mo	de of Oper	atron				·
Chnical Application Anatomy Region of Interest	. В	М	PW Doppler	CW Doppler	Color Doppler	Calor M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes
Ophthalmic							,				
Fetal / Obstetrics ^[7]	P	P	Р		P	P	P	P	P	P	[3.6]
Abdominal ^[1]						_	-				
Pediatric											
Small Organ ¹²¹											
Neonatal Cephalic											
Adult Cephalic]							
Curdiac ¹³											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial		-									
Other											
Exam Type, Means of Access		•									
Transesophageal											
Transrectal ^[4]	P	P	P		P	P	P	P	P	P	[5.6]
Transvaginal	P	Р	Р		P	P	P	P	P	Р	[5,6]
Transuretherul											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											L

N = new indication; P = previously cleared by FDA. E = added under Appendix E

Notes: [5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of folliele development

[8] Includes urology/prostate

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Page 9 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with 9L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mo	de of Oper	นเาดท				
Clinical Application Anatomy Region of Interest	В	М	PW. Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other {Notes}
Ophthalmic -											
Fetal / Obstetrics ⁽⁷⁾	E	E	E	E	E	E	E.	E	E	E	[6]
Abdominal ^{it}											
Pediatric	P	P	P	P	Р	P	P	P	P	P	[6]
Small Organ ¹²¹	P	P	P	P	P	P	P	P	P	Р	[6]
Neonatal Cephalic											
Adult Cephalic					<u> </u>						
Cardiac ¹⁴					l			<u> </u>			
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional	P	P	ь	P	P	P	Р	P	P	P	[6]
Musculo-skeletal Superficial	_										
Other			<u> </u>								
Exam Type, Means of Access			<u>.</u> .		ļ						
Transesophageal			<u> </u>								<u> </u>
Transrectal			<u> </u>	<u> </u>							
Transvaginal		L									
Transuretheral			<u> </u>								
Intraoperative			<u> </u>								
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA. E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

- [6] Includes imaging of guidance of biopsy (2D)
- [7] Includes intertility monitoring of follicle development
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Page 10 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form GE Voluson E Series with P2D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color	Color M			Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics ¹⁷											
Abdominal ^[1]											
Pediatric											
Small Organ ⁽²⁾					<u> </u>						
Neonatal Cephalic			<u> </u>								
Adult Cephalic				P							
Cardiac ^Q				Р							
Peripheral Vascular				Р				<u> </u>			
Musculo-skeletal Conventional			<u> </u>					ļ. —			<u> </u>
Musculo-skeletal Superficial			<u> </u>								<u> </u>
Other			<u> </u>	<u> </u>	<u> </u>						
Exam Type, Means of Access											
Trunsesophageal			<u> </u>	<u></u>							
Transrectal			J					ļ			
Transvaginal			<u>.</u>	<u></u>							
Transuretherul				<u></u>							<u> </u>
Intraoperative					L						ļ
Intraoperative Neurological											ــــــ
Intravascular				L							<u> </u>
Laparoscopic											<u> </u>

N = new indication, P = previously cleared by FDA; E = added under Appendix E

Notes. [3] Cardiac is adult and Pediatric

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Page 11 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form <u>GE Voluson E Series with P6D Transducer</u>

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Мо	de al Oper	ation				
Clinical Application Anotomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other [Notes
Ophthalmic											
Fetal / Obstetrics ⁽¹⁾	<u> </u>										
Abdominal ⁽¹⁾								<u> </u>			
Pediatric											
Small Organ ⁽²⁾		<u> </u>					_				
Neonatal Cephalic	_	<u> </u>	<u> </u>								
Adult Cephalic		<u> </u>	<u> </u>								
Cardiac ¹¹			<u> </u>	Р					_		
Peripheral Vascular				P							
Musculo-skeletal Conventional			<u> </u>								
Musculo-skeletal Superficial			<u> </u>								L
Other			ļ								
Exam Type, Means of Access											
Transesophageal											ļ
Transrectal	<u>.</u>	<u> </u>	1								
Transvaginal											
Transuretherol											
Intraoperative											<u> </u>
Intraoperative Neurological											
Intravasculur											
Laparoscopic			l								

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is adult and Pediatric

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Page 12 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with 11L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Ma	de of Oper	ation	· ·			
Clinical Application Anatony Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic					_						
Fetal / Obstetrics(*)											
Abdominal ⁽¹⁾											
Pediatric	Р	P	P	<u> </u>	Р	P	P	P	Р	P	[6.9]
Smull Organ ^[2]	Р	P	Р		P	P	P	p	P	P	[6,9]
Neonatal Cephalic											
Adult Cephalic								İ			
Cardiac ^{i ()}											
Peripheral Vascular	P	P	P		P	P	P	P	Р	P	[6,9]
Musculo-skeletal Conventional	Р	P	P		P	Р	P	P	P	P	[6.9]
Musculo-skeletal Superficial	P	P	P		Р	P	P	Р	P	P	[6,9]
Other											
Exam Type, Means of Access					<u> </u>	<u></u>					
Transesophageal											
Transrectal		<u> </u>			ļ		,				
Transvaginal	!	_									
Transuretheral			<u> </u>			ļ <u>.</u>					
Intraoperative						<u> </u>					<u> </u>
Intraoperative Neurological		<u></u>	1		<u> </u>						
Intravascular				<u></u>		<u> </u>		ļ			<u> </u>
I.aparoscopic			<u>L</u>			<u></u>		<u> </u>			L

N = new indication, P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[6] Includes imaging of guidance of biopsy (2D)

[9] Elastography Imaging- Elasticity

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Page 13 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form **GE Voluson E Series with C1-5-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mod	de of Oper	ation				
Clinical Application Anatomy/Region of Interest	8	М	PW Doppler	CW Doppler	Color Duppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^(*)	ľ	P	P	P	Р	P	P	P	P	P	[6]
Abdominal ⁽¹⁾	P	ľ	Р	Р	p	P	Р	Р	P	P	[6]
Pediatric				<u> </u>	ļ						
Small Organ ⁽²⁾		ļ	ļ <u> </u>	<u> </u>							
Neonatal Cephalic			<u> </u>						,		
Adult Cephalic											
Cardiae ¹³			<u>. </u>		<u> </u>				_		
Peripheral Vascular	P	P	P	P	P	P	Р	Р	P	P	[6]
Musculo-skeletal Conventional					<u> </u>					<u> </u>	<u> </u>
Musculo-skeletal Superficial			<u> </u>	<u></u>							<u> </u>
Other			<u>.</u>								ļ
Exum Type, Means of Access			<u> </u>							<u> </u>	ļ
Transesophageal		ļ	<u> </u>	L	Ļ					<u> </u>	ļ
Transrectal			<u> </u>	<u> </u>							
Transvaginal										ļ	ļ
Transuretheral			<u> </u>								ļ
Intraoperative			<u> </u>								<u> </u>
Intraoperative Neurological				L	_					ļ	<u> </u>
Intravascular										<u> </u>	
Laparoscopic				<u> </u>						<u> </u>	<u></u>

N = new indication; P = previously cleared by FDA: E = added under Appendix E

- Notes [1] Abdominal includes renal, GYN/Pelvic, Urology
 - [6] Includes imaging of guidance of biopsy (2D)
 - [7] includes intertility monitoring of follicle development
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Concurrence of CDRH, Office of In Vitro Dingnostics and Radiological Health (OIR)

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Page 14 of 24

Diagnostic Ultrasound Indications for Use Form



510(k) Premarket Notification Submission

GE Voluson E Series with ML6-15-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	•			· -	Mod	de af Oper	ation				
Clinical Application Anatomy Region of Interest	В	M	PW Doppler	CW Duppler	Color Doppler	Culor M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic	•										
Fetal / Obstetrics ^(*)											
Abdominal ^[1]											
Pediatric	P	P	Р		Р	Р	Р	P	P	P	[6,9]
Small Organ ⁽²⁾	P	Р	P		Р	P	Р	P	P	Р	[6,9]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ⁽¹⁾											
Peripheral Vascular	P	P	P		P	P	P	P	P	Р	[6,9]
Musculo-skeletal Conventional	P	Р	Р		P	Р	Ρ,	1	P	۴	[6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[6.9]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal			<u> </u>	L							
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											l

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[6] Includes imaging of guidance of biopsy (2D)

[9] Elastography Imaging-Elasticity

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)

Page 15 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RM6C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mo	de of Oper	ation			•	
Clinical Application Anatomy Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Duppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetries ⁽⁵⁾	P	Р	P		P	P	Р	Р	P	P	[5,6]
Abdominal ^(t)	P	Р	P	L	P	P	P	P	P	P	[5.6]
Pediatric	P	P	P		P	Р	P	P	₽	P	[5.6]
Small Organ ^[2]											<u> </u>
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[1]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		Р	P	Р	Р	P	P	[5,6]
Musculo-skeletal Superficial						_					
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal				<u> </u>						_	
Transvaginal	•										
Transuretheral		_						<u></u>			
Intraoperative							•				
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N ≠ new indication, P = previously cleared by FDA. E = added under Appendix E

Notes [1] Abdominal includes renal, GVN3'elvic, Urology

- [5] 3D/4D Imaging Mode
- [6] Includes imaging of guidance of biopsy (3D/4D)
- [7] Includes infertility monitoring of follicle development
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)

Page 16 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RRE5-10-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					М	ide of Ope	eration				
Clinical Application Anatonn Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ⁽¹⁾					L						
Pediatric					L		ļ				
Small Organ ⁽²⁾											
Neonatal Cephalic											
Adult Cephalic			L								
Cardiae ¹³											
Peripheral Vascular				<u> </u>	<u></u>						
Musculo-skeletal Conventional						<u> </u>	ļ				
Musculo-skeletal Superficial				<u> </u>	<u> </u>		.				
Other			<u> </u>								ļ <u>.</u>
Exam Type, Means of Access			<u> </u>			ļ <u>.</u>					
Transesophageal			<u> </u>			<u> </u>	ļ. <u>.</u>				
Transrectat ^[#]	P	P	P		Р	P	Р	Р	Р	P	[5,6,9]
Transvaginal	P	P	Р		P	P	P	P	Р	P	[5,6,9]
Transuretheral			<u> </u>				<u> </u>				
Intraoperative			Ĺ	<u> </u>	<u> </u>						
Intraoperative Neurological			<u> </u>			<u> </u>	ļ				
Intravascular			<u> </u>		<u> </u>	<u> </u>					
l.aparoscopic			<u> </u>	L	<u> </u>		<u> </u>				<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[8] includes urology/prostate

[9] Elastography Imaging- Elasticity

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Page 17 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RM14L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	 	·			Mu	de of Oper	ation				
Clinical Application Anatomy Region of Interest	В	м	PW Doppler	CW Doppler	Color Doppler	Color M		Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic		<u></u>]		<u> </u>						
Fetal / Obstetrics ^[1]											
Abdominal ⁽¹⁾											
Pediatrie	P	Р	₽		Р	P	Р	P	P	P	[5.6]
Small Organ ^{t21}	p	Р	4		P	P	P	Р	P	۴	[5.6]
Neonatal Cephalic		<u> </u>						_			
Adult Cephalic					<u> </u>						<u> </u>
Cordiac ^[3]											
Peripheral Vascular	Р	P	P		Р	P	P	Р	P	Р	[5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial	۲	P	P		Р	P	P	Р	P	p	[5,6]
Other			l								
Exam Type, Means of Access											
Transesophageal			<u> </u>								L
Transrectal			<u> </u>				_				
Transvaginal									·		
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											Ĺ

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[*] Combined modes are B/M, B/Culor M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Page 18 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with 3Sp-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Мо	de of Oper	ation				
Clinical Application Auutomy Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^(*)	Р	Р	P	P	P	P	P	P	P	P	
Abdominal ⁽¹⁾	P	P	P	P	P	P	P	P	₽	P	<u> </u>
Pediatric	P	P	P	P	Р	P	P	P	P	P	
Small Organ ^{ia}											<u> </u>
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	Р	P	P	P	
Cardiac ^{t VI}	P	Р	Р	P	Р	P	Р	P	P	P	
Peripheral Vascular			<u>] </u>		<u> </u>						
Musculo-skeletal Conventional					<u> </u>						
Musculo-skeletal Superficial		<u> </u>	<u></u>								
Other		<u> </u>	<u> </u>								L
Exam Type, Means of Access			L								
Transesophageal											ļ
Transrectal											
Transvaginal		<u> </u>									
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular		<u> </u>	<u> </u>								<u> </u>
Laparoscopic											

N = new indication, P = previously cleared by FDA. E = added under Appendix E

Notes

[1] Abdominal includes renal, GYN/Pelvic

[3] Cardiac is adult and Pediatric

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Culor M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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Page 19 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with C4-8-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Мо	de of Oper	ation				
Clinical Application Anatomy/Region of Interest	В	м	PW Doppler	(W Doppler	Cotor Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic					<u> </u>						
Fetal / Obstetrics ⁽³⁾	P	Ρ	P	P	Р	Р	P	P	Р	P	[6]
Abdominal ⁽¹⁾	Р	P	P	P	Р	Р	P	Р	Р	Р	[6]
Pediatric	P	P	Ъ	Р	Р	P	P	P	Р	P	[6]
Small Organ ⁽²⁾											ļ.,
Neonatal Cephalic			<u> </u>			<u> </u>					
Adult Cephalic					<u></u>	<u> </u>					
Cardiae ¹³ f				<u></u> .							
Peripheral Vascular	P	P	Р	P	P	P	Р	Р	P	Р	[6]
Musculo-skeletal Conventional			<u> </u>								<u> </u>
Musculo-skeletal Superficial		<u> </u>				<u> </u>	<u> </u>	ļ			
Other						ļ	ļ <u>.</u>				
Exam Type, Means of Access		ļ	<u> </u>				<u> </u>	L	_		
Transesophageal						ļ	Ļ			<u> </u>	
Transrectal				ļ	<u> </u>	ļ	<u> </u>		L	ļ	
Transvaginal		ļ.,						ļ			<u> </u>
Transuretherul							ļ. <u> </u>			<u> </u>	
Intraoperative		ļ			<u> </u>						
Intraoperative Neurological		ļ	ļ		ļ	ļ <u> </u>				ļ. —	
Intravascular		<u> </u>					ļ <u> </u>	<u> </u>	L		
1_aparoscopic			l		L		L		<u> </u>	<u></u>	<u></u>

N ≈ new indication, P = previously cleared by FDA. E ≈ added under Appendix E.

- Notes. [1] Abdominal includes renal, GYN/Pelvic, Urology
 - [6] Includes imaging of guidance of biopsy (2D)
 - [7] Includes infertility monitoring of follocle development
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)

Page 20 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RAB6-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mo	de of Oper	ation				
Clinical Application Anatony Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Cofor M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic			<u> </u>								
Fetal / Obstetrics ^(*)	P	P	P	Р	P	P	P	P	P	P	[5.6]
Abdominal ^[1]	P	P	Р	P	P	₽	P	P	₽	P	[5,6]
Pediatric	P	Р	P	Р	Р	P	P	P	P	Р	[5,6]
Small Organi ²¹			<u>l</u>								L
Neonatal Cephalic											
Adult Cephatic											
Cardiac ^{P4}											
Peripheral Vascular											
Musculo-skeletal Conventional	P	Р	P	P	Р	P	P	P	Р	P·	15.61
Musculo-skeletal Superficial					<u> </u>						
Other			<u> </u>								
Exam Type, Means of Access					_						
Transesophageal				<u> </u>	ļ		- <u></u>	ļ			
Transrectal				<u> </u>				<u> </u>			
Transvaginal								<u> </u>			
Transuretheral			<u> </u>					<u> </u>		<u> </u>	
Intraoperative			· ·							ļ	<u> </u>
Intraoperative Neurological								<u> </u>		ļ	
Intravascular			<u> </u>					L			
Laparoscopic						l	-	<u>.</u>	l	[

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Utology [5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD. B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)

Page 21 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with eM6C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mo	de of Oper	ation				
Clinical Application Anatomy Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic			<u>]</u>	<u> </u>	<u></u>						
Fetal / Obstetries ^(*)	P	P	P		P	P	Р	P	P	₽	[5.6]
Abdominal ¹¹	Р	Р	P		Р	Р	P	P	P	Р	[5.6]
Pediatric	P	P	P	ļ <u>.</u>	Р	P	Р	Р	Р	P	5,61
Small Organ ⁽²⁾					<u> </u>			<u> </u>			
Neonatal Cephalic			<u> </u>	<u> </u>	ļ						
Adult Cephalic				<u> </u>	<u> </u>					<u> </u>	ļ <u>.</u>
Cardiac ^[1]			<u> </u>	<u></u>							
Peripheral Vascular											
Musculo-skeletal Conventional	P	₽	Р		P	P	Р	Р	P	P	[5.6]
Musculo-skeletal Superficial			<u> </u>								
Other		ļ	<u> </u>		L			<u> </u>			
Exam Type, Means of Access			<u> </u>		<u> </u>		<u> </u>				<u> </u>
Transesophageal			<u> </u>								ļ
Transrectal							Ļ	<u> </u>			<u> </u>
Transvaginal			<u> </u>				ļ	ļ			
Transuretheral					ļ			ļ	ļ		ļ
Intraoperative	•		<u> </u>					<u> </u>			ļ
Intraoperative Neurological		<u> </u>		<u> </u>	ļ			 			
Intravascular			1	<u> </u>			ļ				
Laparoscopic		l						<u> </u>		<u> </u>	<u> </u>

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Notes [1] Abdominal includes renal, GYN/Pelvic, Urology

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes intertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

[4D cotor Doppler

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Page 22 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with \$4-10-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

L					Mo	le of Oper	ation			,	
Clinical Application Anatomy Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other [Notes
Ophthalmic]		4					
Fetal / Obstetrics ⁽⁷⁾	P	P	P	P	Р	P	P	Р	P	P	Ì
Abdominaliii	P	P	P	P	P	Р	P	P P	P	P	
Pediatric	P	P	P	Р	Р	P	P	P	Ρ	P	
Small Organ ^{E1}	Р	Р	Р	P	P	P	P	P	P	P	<u> </u>
Neonatal Cephalic	Р	ľ	1 12	Р	ч	Р	P	P	þ	P	
Adult Cephalic			 	i							
Cardiac ¹¹	P	Р	P	P	P	Р	Р	Р	P	Р	
Peripheral Vascular	_		1	<u> </u>							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ¹⁴											ļ
Exam Type, Means of Access			<u> </u>]					
Transesophageal			<u> </u>							<u> </u>	└
Transrectal ^[8]								<u> </u>	<u> </u>	ļ	ļ
Transvaginal						<u> </u>				<u> </u>	<u> </u>
Transuretheral							<u> </u>			ļ	<u> </u>
Intraoperative			ļ					<u> </u>		ļ <u>. </u>	
Intraoperative Neurological					<u> </u>					<u> </u>	ļ
Intravascular								1			<u> </u>
Laparoscopic					1	1					L

N = new indication; P = previously cleared by FDA;

Notes

- [1] Abdominal includes renal, GYN/Pelvic, Urology
- [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
- [3] Cardiac is Adult and Pediatric
- [7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Prescription User (Per 21 CFR 801.109)

Page 23 of 24



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RAB4-8-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy: Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Calor M Doppler	Pawer Doppler	Combined Modes	Harmonic Imaging	C'oded Pulse	Other [Notes
Ophthalmic			1								
Fetal / Obstetrics ⁽⁷⁾	E	E	E		Е	F.	£.	E.	E	E	[5.6]
Abdominal ⁽¹⁾	E	E	E		E	E	Ε	E	E	F.	[5,6]
Pediatric	ε	E,	£		E	£	. ε	E	E	E	[5,6]
Small Organ ⁽²⁾											
Neonatal Cephalic											
Adult Cephalic											
Curdiac ¹⁹											
Peripheral Vascular											<u> </u>
Musculo-skeletal Conventional	E	E	E.		F.	Ε	E	E	E	E	[5,6]
Musculo-skeletal Superficial					<u> </u>				ļ		
Other			<u> </u>			<u> </u>	<u> </u>	·	ļ		ļ
Exam Type, Means of Access			<u> </u>						ļ		<u> </u>
Transesophageal					<u> </u>	<u> </u>				ļ	ļ
Transrectal		<u> </u>					ļ	ļ <u>.</u>		ļ	ļ
Transvagmal			<u> </u>	<u> </u>							[
Transuretheral							ļ	ļ		ļ. <u>.</u>	ļ
Intraoperative					<u> </u>	<u> </u>		ļ	<u> </u>		
Intraoperative Neurological		<u></u>			ļ	ļ. <u>.</u>	<u> </u>	<u> </u>		ļ	ļ
Intravascular					ļ			<u> </u>	 	ļ	L
Laparoscopic]	6		<u> </u>	ļ	<u> </u>	_	<u> </u>	<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E (Previously cleared K122327)

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Vol	s:	[1] Abdominal	inch	ides	renal, GYN/Pelvic	
		1 4 1 B 4 5 2 4 4 5 4				

[5] 3D/4D Imaging Mode

510(k) Number K132913

- [6] Includes imaging of guidance of biopsy (3D/4D)
- [7] Includes infertility monitoring of follicle development
- [*] Combined mades are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Page 24 of 24